

**REMARKS**

Claim 68 is amended herein to limit Rings A and E such that formula (I-B) reads on preferred embodiments of the claimed invention and claim 70 is canceled. Support is found, for example, at page 46, first paragraph and page 47, fourth paragraph, of the specification as filed. No new matter is presented.

**I. Response to Claim Rejection - 35 U.S.C. § 112**

Claims 68 and 69 are rejected under 35 U.S.C. §112, first paragraph, allegedly because the specification does not reasonably provide enablement for all ring groups listed within Claim 1 other than where  $t=0$  and Ring A, Ring B and Ring D are phenyl rings. The Examiner's position is set forth at pages 2-5 of the Action.

Essentially, it is the Examiner's position that there is only one working example of a compound within the scope of the elected invention of compounds of formula (I-B) and no other working examples are provided of any compounds, compositions or pharmaceutically acceptable salts where the ring systems or variables are different from those found to be enabled.<sup>1</sup>

Applicants traverse the rejection.

The present rejection is similar to the §112, 1<sup>st</sup> paragraph, lack of enablement rejection raised in the Office Action dated April 5, 2007, with respect to claims 1, 2 and 68 pending at that time. In that Action, the Examiner correctly identified the compound of Example 31 at page 152

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<sup>1</sup> At page 3, lines 15-17 of the Action, the Examiner makes a comment regarding a lack of evidence that solvates exist. However, the present claims do not recite "solvates" and this statement does not appear to be relevant to the present application. Applicants respectfully request clarification of this matter for the record.

as the only exemplary compound of the working examples within the scope of formula (I-B) recited in the claims. The Examiner also considered the disclosure of the synthesis of this compound based on the compound of Example 8(8), Reference example 4, Reference example 5 and Example 7, but the Examiner did not mention the compound of Example 8, which is also referred to in the synthesis of the compound of Example 8(8) at page 138, lines 16-21 (see e.g., pages 4-8 of the Action dated April 5, 2007). The rejection was subsequently withdrawn in the Action dated December 11, 2007 in view of the cancellation of claim 1 and the arguments presented in the Amendment filed October 4, 2007.

It appears that the Examiner is reinstating the lack of enablement rejection as set forth in the present Action with respect to current claim 68. Applicants disagree for the reason of record, which are incorporated herein. Namely, in making a determination of enablement, the proper inquiry is whether one of ordinary skill in the art would be able to use the claimed invention without undue experimentation. There are several factors which must be weighed and considered to determine whether any necessary experimentation can be considered as undue: (1) the breadth of the claims; (2) the nature of the invention; (3) the state of the prior art; (4) the level of one of ordinary skill in the art; (5) the level of predictability in the art; (6) the amount of direction provided by the inventor; (7) the existence of working examples; and (8) the quantity of experimentation needed to make and use the invention based upon the disclosure. See MPEP § 2164.01(a).

The PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by the claim is not adequately enabled by the description of the invention provided in the specification of the application; this includes,

providing sufficient reasons for doubting any assertions in the specification as to the scope of enablement. Applicants submit that the Examiner has not met his burden of providing a reasonable basis to question the enablement provided for the claimed invention. See also MPEP § 2164.01 and § 2164.04.

The Examiner asserts that there is only one example of compounds in the specification which is included within the scope of formula (I-B). However, Applicants respectfully disagree with the Examiner's assertion that the enablement requirement is not satisfied since considerable numbers of the compounds within the scope of formula (I-B) can be produced according to the examples and general production method described in the present specification.

First, Applicants are not limited by the synthesis examples in the specification. So even if there is only one representative compound of formula (I-B) in the specification, the claimed compounds would be enabled as long as one of ordinary skill in the art would be able to make and use other compounds within the scope of the claims based on the description that is provided in the specification and knowledge and skill available in the art.

Further, the Examiner's statement that only one compound within the scope of formula (I-B) is synthesized is not the proper test. A specification may be enabling without any working examples. See MPEP § 2164.02.

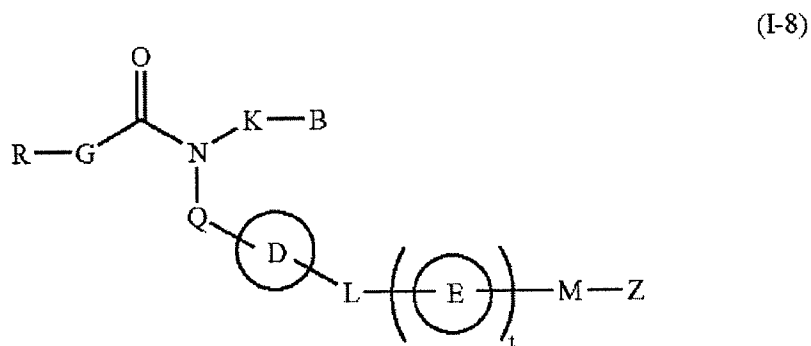
Applicants submit that the synthesis disclosure referred to by the Examiner, the disclosure at pages 57-70 and the exemplary compounds in the present specification provide sufficient guidance for those of ordinary skill in the art to make the claimed compounds.

Namely, it is described that the compound of Example 31 can be produced based on the compound of Example 8(8) and the compound of Example 8(8) can be produced in accordance

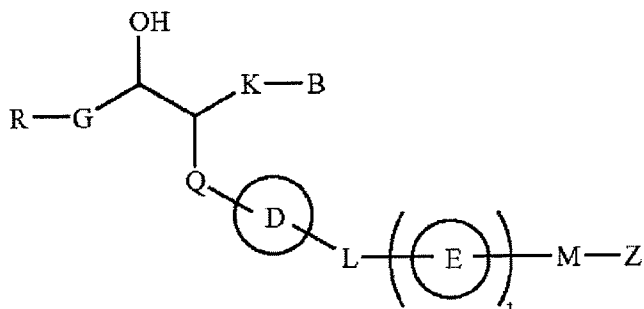
with the compound of Example 8. Therefore, the present specification provides sufficient guidance for a person ordinarily skilled in the art to produce the compound within the scope of formula (I-B) in which t is 1 and ring E is phenyl.

Further, it is disclosed in the specification that the compound within the scope of formula (I-B) can be produced in accordance with the general method represented by formula (I-8-3). It is described that whatever ring, the ring A, ring B, ring D and ring E represent, the compound of formula (I-8-3) can be produced by subjecting the carbonyl group of the compound of formula (I-8) to reduction then protection. Moreover, it is described that the compound of formula (I-8) can be produced by subjecting the compounds of formulas (11) and (12) to a reaction. Thus, the claimed invention is sufficiently enabled.

Specifically, at page 67, it is disclosed that compounds of formula (I-8-3) can be produced by subjecting the carbonyl group of the compound of formula (I-8) (at page 66) to reduction and then deprotection. Formula (I-8) and formula (I-8-3) are provided below:



(I-8-3)



The reduction of the carbonyl group is said to be conventionally known and there are several examples of compounds in the specification within the scope of formula (I-8) above. Thus, one of ordinary skill in the art could make compounds within the scope of formula (I-8-3) by performing conventional reduction of the carbonyl group as taught in the specification.

Further, the compounds of Examples 7 and 8, from which the claimed compound can be made, include ring (E) wherein  $t$  is 1 and based on these examples, the teachings in the specification and the knowledge and skill available in the art, one of ordinary skill in the art could readily make similar compounds within the scope of formula (I-B) wherein  $t$  is 1.

Moreover, the original specification and claims provide examples wherein ring B and ring D are other than a phenyl ring and based upon the knowledge and skill available in the art, the exemplary compounds and the teachings in the present specification, one of ordinary skill in the art would readily make similar compounds within the scope of the present claims.

Even further, the examples provided in the Rule 132 Declaration submitted October 4, 2007, further support the enablement of the claimed invention by showing that the compounds disclosed in the Declaration were made according to the teachings in the present specification.

The Declaration shows that even if ring B and ring D are other than phenyl, similar pharmacological activity is exerted. Also, ring A and ring E are limited to preferred embodiments of the invention.

Accordingly, the claimed invention is sufficiently enabled and withdrawal of the rejection is respectfully requested.

## **II. Response to Claim Objection**

In paragraph 5 of the Action, the Examiner indicates that if claim 69 is found allowable, claim 70 will be objected to as a substantial duplicate of claim 69. The Examiner states that the recitation of intended use, chemical activity or functional description of an additional property of a compound is not given patentable weight if there is no tangible structural difference. In the absence of a tangible structural difference claim 70 is not considered to further limit claim 69 and would be considered as a substantial duplicate of claim 69.

Claim 70 is canceled herein, thereby rendering the objection moot.

## **III. Response to Obviousness-Type Double Patenting Rejection**

In paragraph 6 of the Action, the Examiner notes that Applicants have requested that the obviousness-type double patenting rejection in the Action dated July 25, 2008 based on claim 1 of U.S. Publication No. 2007/0149595 be held in abeyance. The Examiner agrees that the present application is the earlier filed application and indicates that the obviousness-type double patenting rejection in the present application will be withdrawn if it is the only rejection remaining.

Applicants respectfully defer responding until allowable subject matter is indicated by the Examiner. Applicants further note that the present application was earlier filed and if the only rejection remaining in this application is the provisional obviousness-type double patenting rejection, the Examiner should withdraw the rejection in this application and allow the present application to issue.

Accordingly, Applicants request withdrawal of the provisional obviousness-type double patenting rejection.

#### **IV. Conclusion**

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

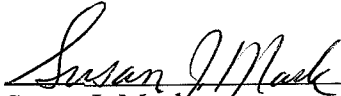
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